"Is the Sky Falling?"

Prosecution and Defense of Complaints Against APRN Prescription Practices

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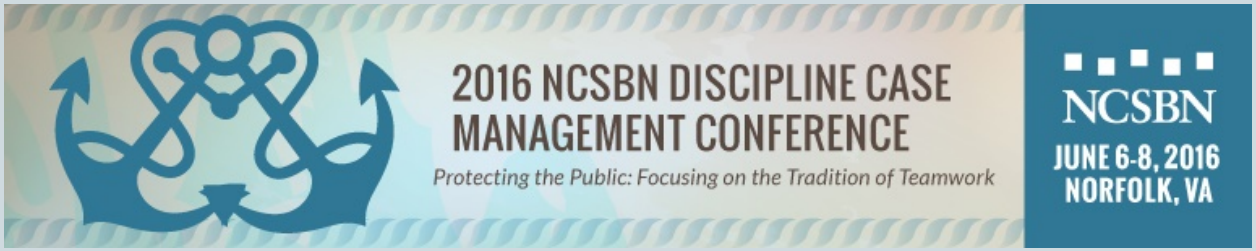
June 8, 2016



Introduction

Diversion and “doctor shopping” accounts for 40% of drug overdose deaths. To address the dual issues of access to appropriate pain management and opioid-related adverse outcomes, prescribers have dual obligations: to manage pain and improve function while reducing problems resulting from misuse and abuse of prescription opioids in the patient and community.

Source:

COLORADO
Department of
Regulatory Agencies

Policy for Prescribing and Dispensing Opioids

Colorado Dental Board, Colorado Medical Board, State Board of Nursing, and State Board of Pharmacy

Introduction

Eighteen years of studies show that APRNs do it better

A meta-analysis released in *Nursing Economic$* stretching over 18 years compared care provided by advanced practice registered nurses (APRNs) to care provided by physicians. Care was compared in 24 different categories.

- APRNs performed equal to physicians in 13 categories.
- APRNs performed better than physicians in 11 categories.
- Physicians performed better than APRNs in zero categories

Source:

http://www.truthaboutnursing.org/faq/aprn_md.html#ixzz46xCQRchh

Introduction

Advanced Practice Nurse Prescription Practices

Introduction

Uncertainty regarding potential disciplinary action may give physicians pause when considering whether to accept a chronic pain patient or how to treat a patient who may require long-term or high doses of opioids. Surveys have shown that physicians fear potential disciplinary action for prescribing controlled substances and that physicians will, in some cases, inadequately prescribe opioids due to fear of regulatory scrutiny. Prescribing opioids for long-term pain management, particularly noncancer pain management, has been controversial; and boards have investigated and, in some cases, disciplined physicians for such prescribing.

Source: Diane E. Hoffmann & Anita J. Tarzian, *Achieving the Right Balance in Oversight of Physician Opioid Prescribing for Pain: The Role of State Medical Boards*, 31 J.L. Med. & Ethics 21 (2003)

Introduction

Regulatory Implications of Pain Management

Julia L. George, MSN, RN, FRE; Catherine A. Giessel, MS, RN, ANP, FAANP; Fred Olmstead, JD

Pain management is complex and raises important regulatory issues for boards of nursing (BONs). BONs deal with pain management situations related to both the nurse in pain and the patient in pain. The issues may relate to nurses or advanced practice nurses managing their patients' pain or nurses themselves receiving pain treatment or having dual diagnoses of chemical dependency and pain. To support BONs dealing with these issues, the National Council of State Boards of Nursing developed a national statement identifying the regulatory implications for nursing and presenting best practices that promote regulatory excellence and public protection.

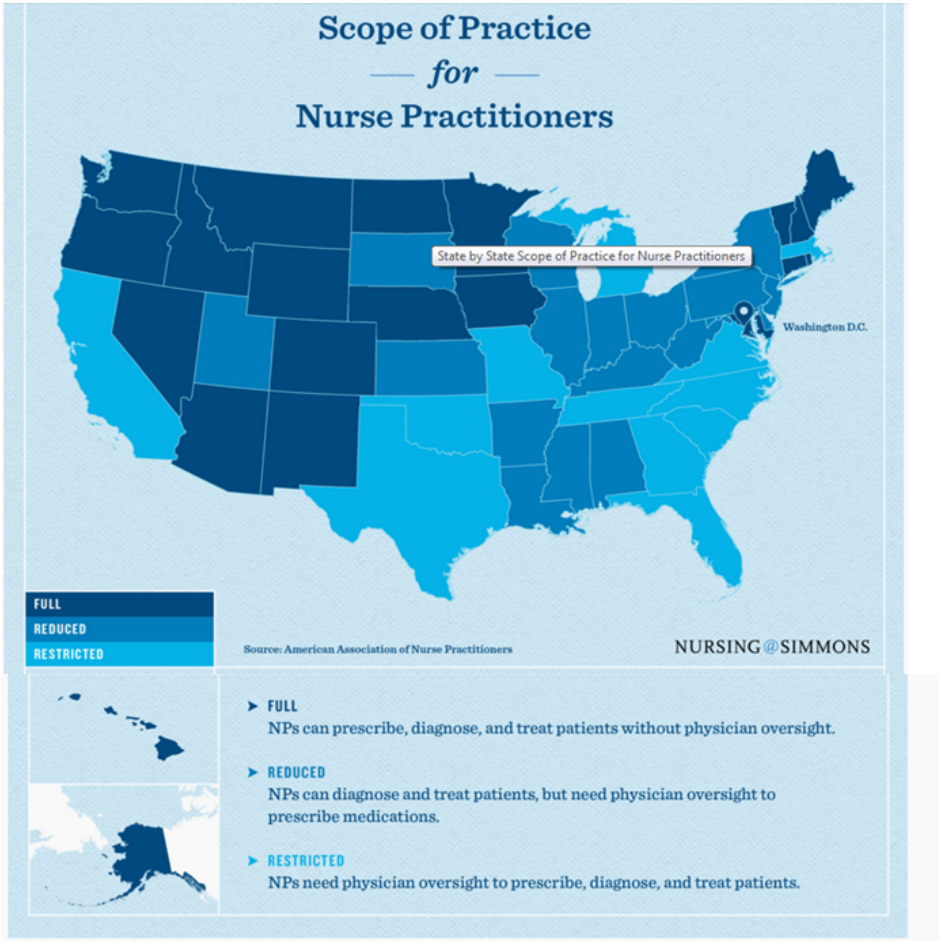
Source:

October 2010
Volume 1, Issue 3, Pages 44–51

Introduction

Introduction

NOT ALL ADVANCED PRACTICE NURSES ARE



Source: https://nursinglicensemap.com/advanced-practice-nursing/nurse-practitioner/nurse-practitioner-prescriptive-authority/

Introduction

Nurse Practitioners have full practice authority in the following states:

Alaska
Arizona
Colorado
Connecticut
District of Columbia
Hawaii
Idaho
Iowa
Maine
Maryland
Minnesota
Montana
Nebraska
Nevada
New Hampshire
New Mexico
North Dakota
Oregon
Rhode Island
Vermont
Washington
Wyoming

Source: https://nursinglicensemap.com/advanced-practice-nursing/nurse-practitioner/nurse-practitioner-prescriptive-authority/

Introduction

THE FACTS

- The director of a state pharmacy board has submitted a complaint against an advanced practice nurse regarding an excessive amount of controlled substances involving two patients.
- Board Executive Director at a "Prescription Drug Abuse" meeting learns from the U.S. Attorney representative about a case the DEA is investigating – a suspicious death by Fentanyl overdose – the decedent obtained Fentanyl from a patient of the advanced practice nurse

Introduction

THE INVESTIGATION

Following investigation, the Investigative Board Member determined that the nurse engaged in practices that deviated from acceptable nurse practice standards.

Nurse was sent a proposed settlement agreement (consent decree) for reprimand and training, which she declined to execute to have a hearing before the Board.

Introduction

THE PROCEDURE

- The expert against the licensee at a hearing will provide direct expert testimony of the standard of care and how deviations occurred related to the three patients
- Cross-examination of the expert will be presented
- Both attorneys will provide closing arguments

DUE PROCESS 101

BASIC RULE:

NOTICE AND OPPORTUNITY TO BE HEARD

Due Process 101

indicating the charges or GROUNDS FOR DISCIPLINE upon which proposed disciplinary action will be based

Due Process 101

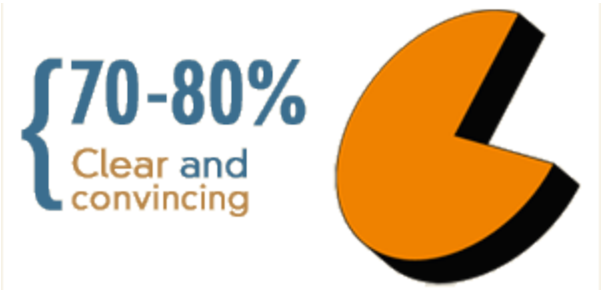
CONTESTED CASE HEARING

DUE PROCESS 101 -- EVIDENCE

BURDEN OF PROOF

Due Process 101 -- Evidence

another
way to look at this
is..



Due Process 101 -- Evidence

or what are the ELEMENTS that must be proven?

FRAMES NOT ONLY WHAT EVIDENCE MUST BE PRESENTED AT A HEARING BUT WHAT EVIDENCE ALSO MUST BE OBTAINED IN INVESTIGATION!

Due Process 101 -- Evidence

Prima Facie Case

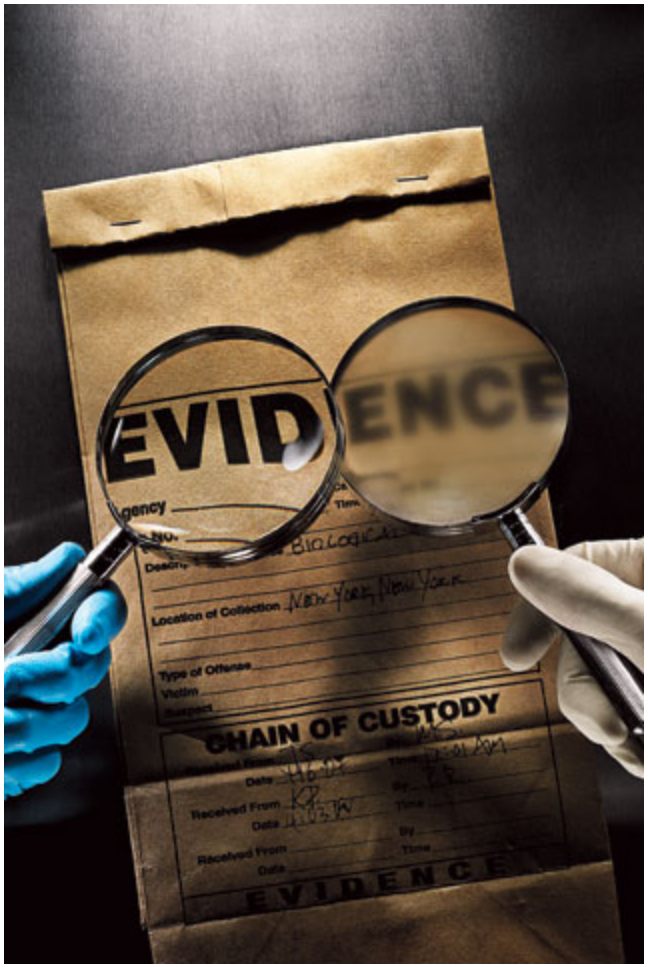
Emergency/Summary Suspension vs. Hearing on the Merits

- **Elements of the underlying ground(s)** (*e.g.*, substandard practice)
- **Substantial likelihood of prevailing at hearing on merits**
- **Nurse presents a clear and immediate danger to public health and safety if permitted to continue to practice.**

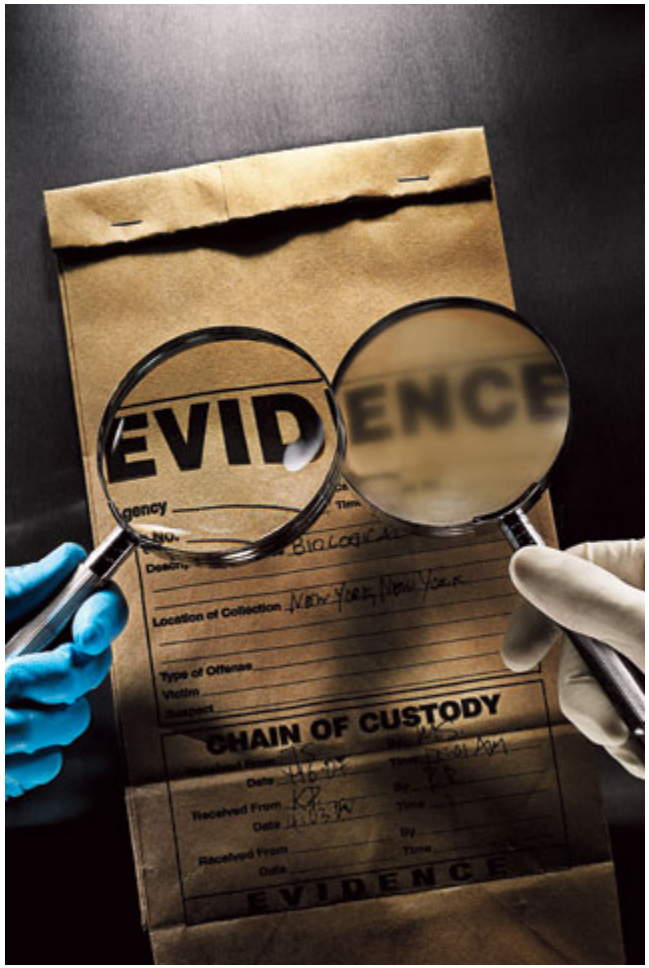
- **Elements of the underlying ground(s)** (*e.g.*, substandard practice)
- **Preponderance or Clear and convincing evidence standard**
- **Sanction imposed by Board is not arbitrary or capricious** (*i.e.*, reasonable under circumstances considering mitigating and aggravating factors)

Due Process 101

Going to need EVIDENCE of the STANDARD OF CARE



Due Process 101

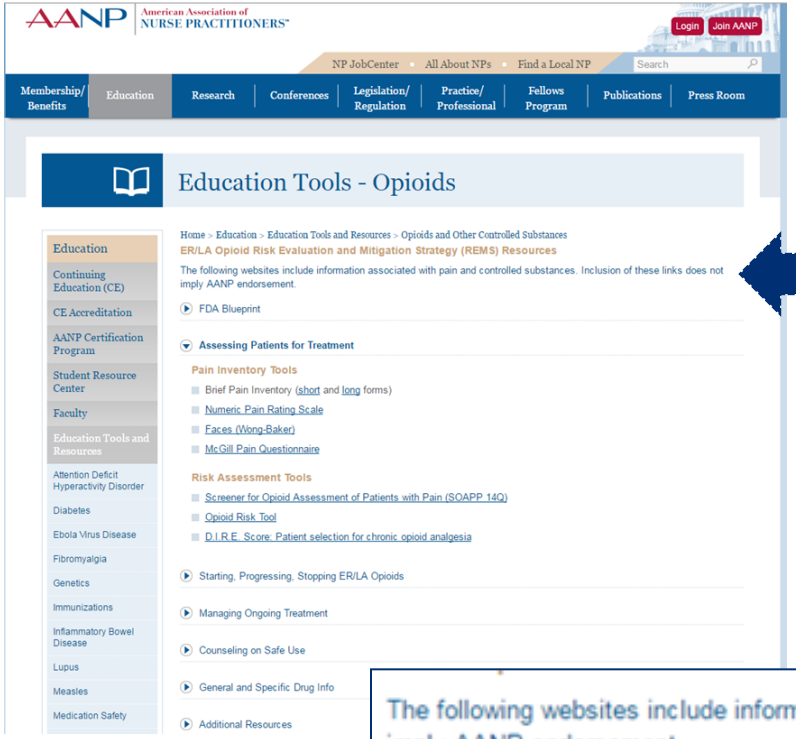


Going to need EVIDENCE of how nurse deviated from STANDARD OF CARE

Due Process 101

Accused nurse has the legal right for opportunity to dispute the charges of substandard practice

STANDARDS?



No position statement!

The following websites include information associated with pain and controlled substances. Inclusion of these links does not imply AANP endorsement.

STANDARDS?

AMERICAN SOCIETY FOR Pain Management Nursing

ASPMN Position Statement
Pain Management in Patients with Addictive Disease

The American Society for Pain Management Nursing (ASPMN) position is that patients with addictive disease and pain have the right to be treated with dignity, respect, and the same quality of pain assessment and management as all other patients. This includes maintaining a balance between provision of pain relief and protection against inappropriate use of prescribed medications. Nurses are well positioned and obligated to advocate for pain management across all treatment settings for patients actively using alcohol or other drugs, patients in recovery, or those receiving methadone for opioid dependence.

Recommendations for *all* patients with addictive disease:

- Identify and use resources available to assist with the diagnosis and treatment of both addiction and pain.
- Encourage the patient to use support systems (e.g., family, significant others, or rehabilitation sponsor); offer additional resources (e.g., addictions counselor).
- Involve the patient in pain management planning and, with the patient's consent, include family and significant others.
- Provide the patient with verbal and written information about the pain management plan, including what the patient can expect from caregivers and what the patient's responsibilities are.
- Ensure consistency in the implementation of the pain management plan.
- Educate the patient, family, and significant others about the differences between addiction, physical dependence, and tolerance.
- Help the patient make informed choices about medications by educating the patient, family, and significant others about medication options.
- Select and titrate analgesics based on pain assessment, side effects, and function, as well as sleep and mood.
- Be prepared to titrate opioid analgesics and benzodiazepines to doses higher than usual. The patient may have developed tolerance to some medications, or drug use may have caused increased sensitivity to pain.
- Benzodiazepines, phenothiazines, or other sedating medications that do not relieve pain should not be used as substitutes for analgesics.
- If pain is present most of the time, provide analgesics around-the-clock (ATC).
- Use the oral route and long acting analgesics when possible.
- Consider the use of IV or epidural patient-controlled analgesia (PCA) for acute pain management.
- Record and discuss with the patient any behavior suggestive of inappropriate medication use, especially of controlled substances.
- When opioids, benzodiazepines, or other medications with a potential for physical dependence are no longer needed, taper them very slowly to minimize the emergence of withdrawal symptoms.
- Consider nonpharmacological methods of treatment for pain but do not use them in place of appropriate pharmacological approaches.

STANDARDS?

AMERICAN NURSES ASSOCIATION

FREQUENTLY ASKED QUESTIONS ABOUT PRESCRIBING CONTROLLED SUBSTANCES

What are some of the legal issues to consider when writing a prescription for a CS?

A legitimate purpose for prescribing a CS must exist and there must be a patient-provider relationship. Federal law prohibits pre-signed prescriptions. You may have an individual prepare a prescription for your signature however you are legally responsible if the prescription does not conform to legal requirements. Document the prescriptions you write. Some states, such as Virginia and Washington State, prohibit self-prescribing of CSs. Some states may also prohibit prescribing CSs for family members. Even if prescribing a CS for oneself or a family member is permitted under certain circumstances, this may not be advisable for professional reasons.

Can I prescribe drugs used for treating opiate addiction?

No. Federal law restricts methadone for the treatment of dependence to legally authorized Opioid Treatment Programs (OTPs). At these sites methadone is administered or dispensed, not prescribed, to patients. NPs may be part of the OTP team if allowed by state law. Methadone is a Schedule II CS that *can* be prescribed by APRNs for pain if authorized by state law. Federal law only allows physicians to offer office based opioid addiction treatment using buprenorphine (Subutex®) and buprenorphine/naloxone (Suboxone®). Buprenorphine is a Schedule III CS that *can* be prescribed by NPs for pain if legally authorized by the state.

What are some of the requirements for prescribing controlled substances that states may have?

As noted above, there are a variety of requirements or restrictions states may impose on APRNs who prescribe CSs. For example, states may:

- Require controlled drug substances registration or licensure
- Require a written agreement between a physician and an APRN
- Restrict the types of CSs that may be prescribed
- Limit or prohibit prescribing CS
- Limit the quantity of a CS prescribed
- Limit the duration for which a CS may be prescribed
- Have a formulary for prescribing CS
- Have guidelines for managing patients receiving opioids for noncancer chronic pain

STANDARDS?

NCSBN
National Council of State Boards of Nursing

111 E. Wacker Drive, Suite 2900
Chicago, IL 60601-4277

312.525.3600
www.ncsbn.org

National Council of State Boards of Nursing
Statement on the Regulatory Implications of Pain Management

Role of the Board of Nursing

Boards of nursing deal with four unique pain management situations:

1. A nurse fails to meet the expected standards of nursing pain management, resulting in the risk of harm and suffering for patients.
2. An advanced practice registered nurse (APRN) fails to appropriately prescribe medications for pain management.
3. A nurse's personal pain or treatment for pain affects his/her ability to practice safely.
4. A chemically dependent nurse requires pharmacologic pain management.

NCSBN fully supports the nursing role in the thorough assessment and effective management of pain. Boards' of nursing mandate of public protection includes a responsibility to protect the public from the mismanagement of pain. Boards also must address the impact that being in pain and receiving pain treatment have on the ability of nurses to practice safely.

Future Steps

Additional resources are planned to provide model policies and guidelines for each of the regulatory issues addressed above. This work will support boards of nursing in meeting the regulatory challenges presented by pain management.

STANDARDS?

Federation of STATE MEDICAL BOARDS

Model Policy on the Use of Opioid Analgesics in the Treatment of Chronic Pain

July 2013

Conclusion: The goal of this Model Policy is to provide state medical boards with an updated guideline for assessing physicians' management of pain, so as to determine whether opioid analgesics are used in a manner that is both medically appropriate and in compliance with applicable state and federal laws and regulations. The revised Model Policy makes it clear that the state medical board will consider inappropriate management of pain, particularly chronic pain, to be a departure from accepted best clinical practices, including, but not limited to the following:

- **Inadequate attention to initial assessment to determine if opioids are clinically indicated and to determine risks associated with their use in a particular individual with pain:** Not unlike many drugs used in medicine today, there are significant risks associated with opioids and therefore benefits must outweigh the risks.

- **Inadequate monitoring during the use of potentially abusable medications:** Opioids may be associated with addiction, drug abuse, aberrant behaviors, chemical coping and other dysfunctional behavioral problems, and some patients may benefit from opioid dose reductions or tapering or weaning off the opioid.

- **Inadequate attention to patient education and informed consent:** The decision to begin opioid therapy for chronic pain should be a shared decision of the physician and patient after a discussion of the risks and a clear understanding that the clinical basis for the use of these medications for chronic pain is limited, that some pain may worsen with opioids, and taking opioids with other substances or certain condition (i.e. sleep apnea, mental illness, pre-existing substance use disorder) may increase risk.

- **Unjustified dose escalation without adequate attention to risks or alternative treatments:** Risks associated with opioids increase with escalating doses as well as in the setting of other comorbidities (i.e. mental illness, respiratory disorders, pre-existing substance use disorder and sleep apnea) and with concurrent use with respiratory depressants such as benzodiazepines or alcohol.

- **Excessive reliance on opioids, particularly high dose opioids for chronic pain management:** Prescribers should be prepared for risk management with opioids in advance of prescribing and should use opioid therapy for chronic non-cancer pain only when safer and reasonably effective options have failed. Maintain opioid dosage as low as possible and continue only if clear and objective outcomes are being met.

- **Not making use of available tools for risk mitigations:** When available, the state prescription drug monitoring program should be checked in advance of prescribing opioids and should be available for ongoing monitoring.

Section II: Guidelines

The Board has adopted the following criteria when evaluating the physician's treatment of pain, including the use of controlled substances:

Evaluation of the Patient—A medical history and physical examination must be obtained, evaluated, and documented in the medical record. The medical record should document the nature and intensity of the pain, current and past treatments for pain, underlying or coexisting diseases or conditions, the effect of the pain on physical and psychological function, and history of substance abuse. The medical record also should document the presence of one or more recognized medical indications for the use of a controlled substance.

Treatment Plan—The written treatment plan should state objectives that will be used to determine treatment success, such as pain relief and improved physical and psychosocial function, and should indicate if any further diagnostic evaluations or other treatments are planned. After treatment begins, the physician should adjust drug therapy to the individual medical needs of each patient. Other treatment modalities or a rehabilitation program may be necessary depending on the etiology of the pain and the extent to which the pain is associated with physical and psychosocial impairment.

Informed Consent and Agreement for Treatment—The physician should discuss the risks and benefits of the use of controlled substances with the patient, persons designated by the patient or with the patient's surrogate or guardian if the patient is without medical decision-making capacity. The patient should receive prescriptions from one physician and one pharmacy whenever possible. If the patient is at high risk for medication abuse or has a history of substance abuse, the physician should consider the use of a written agreement between physician and patient outlining patient responsibilities, including

- urine/serum medication levels screening when requested;
- number and frequency of all prescription refills; and
- reasons for which drug therapy may be discontinued (e.g., violation of agreement).

Periodic Review—The physician should periodically review the course of pain treatment and any new information about the etiology of the pain or the patient's state of health. Continuation or modification of controlled substances for pain management therapy depends on the physician's evaluation of progress toward treatment objectives. Satisfactory response to treatment may be indicated by the patient's decreased pain, increased level of function, or improved quality of life. Objective evidence of improved or diminished function should be monitored and information from family members or other caregivers should be considered in determining the patient's response to treatment. If the patient's progress is unsatisfactory, the physician should assess the appropriateness of continued use of the current treatment plan and consider the use of other therapeutic modalities.

Consultation—The physician should be willing to refer the patient as necessary for additional evaluation and treatment in order to achieve treatment objectives. Special attention should be given to those patients with pain who are at risk for medication misuse, abuse or diversion. The management of pain in patients with a history of substance abuse or with a comorbid psychiatric disorder may require extra care, monitoring, documentation and consultation with or referral to an expert in the management of such patients.

Medical Records—The physician should keep accurate and complete records to include

1. the medical history and physical examination,
2. diagnostic, therapeutic and laboratory results,
3. evaluations and consultations,
4. treatment objectives,
5. discussion of risks and benefits,
6. informed consent,
7. treatments,
8. medications (including date, type, dosage and quantity prescribed),
9. instructions and agreements and
10. periodic reviews.

Records should remain current and be maintained in an accessible manner and readily available for review.

Compliance With Controlled Substances Laws and Regulations—To prescribe, dispense or administer controlled substances, the physician must be licensed in the state and comply with applicable federal and state regulations. Physicians are referred to the Physicians Manual of the U.S. Drug Enforcement Administration and (any relevant documents issued by the state medical board) for specific rules governing controlled substances as well as applicable state regulations.

STANDARDS?

United States Department of Justice
Drug Enforcement Administration
Office of Diversion Control

Practitioner's Manual

An Informational Outline of the
Controlled Substances Act

STANDARDS?

CDC Guideline for Prescribing Opioids for Chronic Pain — United States, 2016

Determining When to Initiate or Continue Opioids for Chronic Pain

1. **Nonpharmacologic therapy and nonopioid pharmacologic therapy are preferred for chronic pain. Providers should only consider adding opioid therapy if expected benefits for both pain and function are anticipated to outweigh risks to the patient (recommendation category: A, evidence type 3).**

2. **Before starting opioid therapy for chronic pain, providers should establish treatment goals with all patients, including realistic goals for pain and function. Providers should not initiate opioid therapy without consideration of how therapy will be discontinued if unsuccessful. Providers should continue opioid therapy only if there is clinically meaningful improvement in pain and function that outweighs risks to patient safety (recommendation category: A, evidence type: 4).**

3. **Before starting and periodically during opioid therapy, providers should discuss with patients known risks and realistic benefits of opioid therapy and patient and provider responsibilities for managing therapy (recommendation category: A, evidence type: 3).**

Opioid Selection, Dosage, Duration, Follow-Up, and Discontinuation

4. **When starting opioid therapy for chronic pain, providers should prescribe immediate-release opioids instead of extended-release/long-acting (ER/LA) opioids (recommendation category: A, evidence type: 4).**

5. **When opioids are started, providers should prescribe the lowest effective dosage. Providers should use caution when prescribing opioids at any dosage, should implement additional precautions when increasing dosage to ≥50 morphine milligram equivalents (MME)/day, and should generally avoid increasing dosage to ≥90 MME/ day (recommendation category: A, evidence type: 3).**

6. **Long-term opioid use often begins with treatment of acute pain. When opioids are used for acute pain, providers should prescribe the lowest effective dose of immediate-release opioids and should prescribe no greater quantity than needed for the expected duration of pain severe enough to require opioids. Three or fewer days usually will be sufficient for most nontraumatic pain not related to major surgery (recommendation category: A, evidence type: 4).**

7. Providers should evaluate benefits and harms with patients within 1 to 4 weeks of starting opioid therapy for chronic pain or of dose escalation. Providers should evaluate benefits and harms of continued therapy with patients every 3 months or more frequently. If benefits do not outweigh harms of continued opioid therapy, providers should work with patients to reduce opioid dosage and to discontinue opioids (recommendation category: A, evidence type: 4).

Assessing Risk and Addressing Harms of Opioid Use

8. Before starting and periodically during continuation of opioid therapy, providers should evaluate risk factors for opioid-related harms. Providers should incorporate into the management plan strategies to mitigate risk, including considering offering naloxone when factors that increase risk for opioid overdose, such as history of overdose, history of substance use disorder, or higher opioid dosages (≥50 MME), are present (recommendation category: A, evidence type: 4).

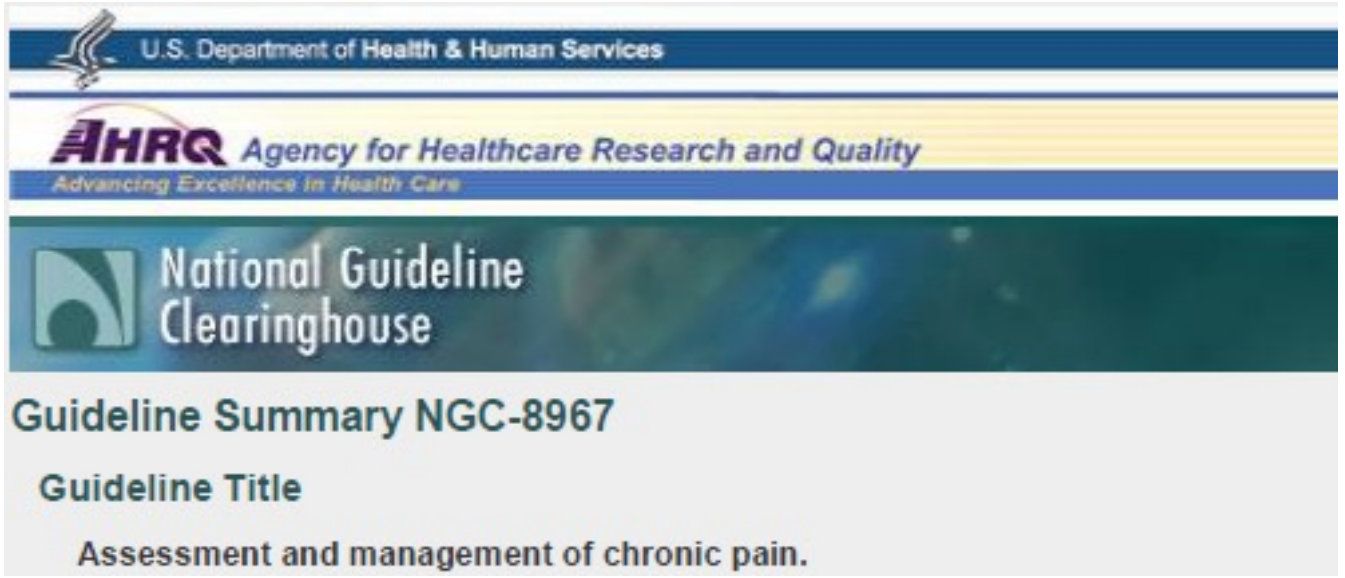
9. Providers should review the patient's history of controlled substance prescriptions using state prescription drug monitoring program (PDMP) data to determine whether the patient is receiving high opioid dosages or dangerous combinations that put him or her at high risk for overdose. Providers should review PDMP data when starting opioid therapy for chronic pain and periodically during opioid therapy for chronic pain, ranging from every prescription to every 3 months (recommendation category: A, evidence type: 4).

10. When prescribing opioids for chronic pain, providers should use urine drug testing before starting opioid therapy and consider urine drug testing at least annually to assess for prescribed medications as well as other controlled prescription drugs and illicit drugs (recommendation category: B, evidence type: 4).

11. Providers should avoid prescribing opioid pain medication for patients receiving benzodiazepines whenever possible (recommendation category: A, evidence type: 3).

12. Providers should offer or arrange evidence-based treatment (usually medication-assisted treatment with buprenorphine or methadone in combination with behavioral therapies) for patients with opioid use disorder (recommendation category: A, evidence type: 3).

STANDARDS?


U.S. Department of Health & Human Services
AHRQ Agency for Healthcare Research and Quality
Advancing Excellence in Health Care
National Guideline Clearinghouse
Guideline Summary NGC-8967
Guideline Title
Assessment and management of chronic pain.

Clinical Highlights

- Chronic pain assessment should include determining the mechanisms of pain through documentation of pain location, intensity, quality and onset/duration; functional ability and goals; and psychological/social factors such as depression or substance abuse. (*Annotations #2, 3, 12; Aim #2*)
- The goal of treatment is an emphasis on improving function through the development of long-term self-management skills including fitness and a healthy lifestyle in the face of pain that may persist. (*Annotation #14, Aim #1*)
- A patient-centered, multifactorial, comprehensive care plan is necessary, one that includes addressing biopsychosocial factors. Addressing spiritual and cultural issues is also important. It is important to have a multidisciplinary team approach coordinated by the primary care physician to lead a team including specialty areas of psychology and physical rehabilitation. (*Annotation #14, Aim #3*)
- Level I treatment approaches should be implemented as first steps toward rehabilitation before Level II treatments are considered. (*Annotation #14; Aim #3*)
- Medications are not the sole focus of treatment in managing pain and should be used when needed to meet overall goals of therapy in conjunction with other treatment modalities. (*Annotations #14, 19; Aims #4, 5*)
- Careful patient selection and close monitoring of all non-malignant pain patients on chronic opioids is necessary to assess the effectiveness and watch for signs of misuse or aberrant behavior. (*Annotation #19; Aim #5*)

Assessment Algorithm Annotations

2. Critical First Step: Assessment

Recommendations:

- All patients should have an adequate pain assessment that includes documentation of pain location, intensity, quality, onset/duration/variations/rhythms, manner of expressing pain, pain relief, what makes it worse, effects of pain, and a pain plan.
- A general history and physical should be completed in assessing chronic pain.

Pharmacologic Management

Recommendations:

- NSAIDs should be used for periodic flare-ups of mild to moderate inflammatory or non-neuropathic pain.
- Clinicians should define the goals of therapy before prescribing medications, and tailor medications to meet the individual goals of each patient.
- Clinicians should identify and treat specific source(s) of pain.
- Clinicians should educate patients about the risks and benefits of all drugs, and watch for and manage side effects.
- For opioid therapy clinicians should:
  - Use caution before starting a patient on long-term opioid therapy.
  - Follow the 4 A's (Analgesia, Adverse drug reactions, Activity, Adherence) *[Guideline]*.
  - The work group recommends the use of a written opioid agreement for patients anticipated to be on long-term therapy. See Appendix F in the original guideline document for an example of an opioid agreement form.

STANDARDS?

A TREATMENT IMPROVEMENT PROTOCOL

Managing Chronic Pain in Adults With or in Recovery From Substance Use Disorders

Substance Abuse and Mental Health Services Administration

SAMHSA

1 Introduction

IN THIS CHAPTER

Chronic Pain Impact

Chronic noncancer pain (CNCP) is common in the general population as well as in people who have a substance use disorder (SUD) (Exhibit 1-1). Chronic pain is not harmless; it has physiological, social, and psychological dimensions that can seriously harm health, functioning, and well-being. As a multidimensional condition with both objective and subjective aspects, CNCP is difficult to assess and treat. Although CNCP can be managed, it usually cannot be completely eliminated. When patients with CNCP have comorbid SUD or are recovering from SUD, a complex condition becomes even more difficult to manage.

Key Points

- CNCP and the disease of addiction involve neurophysiological processes.
- Both genetic and environmental factors contribute to and influence the development and course of CNCP and addiction.
- Clinicians must understand CNCP, addiction, and other behavioral health issues to best serve the chronic pain patient with or in recovery from an SUD.
- Despite the complexities of CNCP and SUDs, patients with these co-occurring, chronic conditions can be treated effectively.

2 Patient Assessment

IN THIS CHAPTER

Elements of Assessment

Researchers and clinicians agree that, because chronic noncancer pain (CNCP) is a multifaceted condition, assessment must include more than measures of pain intensity (Brunton, 2004; Haefeli & Elfering, 2006; Karoly, Ruehlman, Aiken, Todd, & Newton, 2006; Sullivan & Ferrell, 2005). Some elements are essential to assess; others, ideal. In many cases, even after a thorough assessment, the clinician may not detect the nociceptive source of a patient's chronic pain.

Collateral information is an important part of the assessment. Clinicians need to communicate with families, pharmacists, and other clinicians after the patient has given full consent for these discussions. If the patient declines to give consent, prolonged treatment with controlled substances may be contraindicated. Furthermore, a clinician who prescribes controlled substances to a patient who refuses to permit access to outside information could be considered to be ignoring evidence of addiction or substance misuse and, therefore, to be trafficking. Collateral information also helps protect the patient from misusing medications. Exhibit 2-1 presents elements of a comprehensive assessment.

Key Points

- Patients should receive a comprehensive initial assessment.
- It is important to discover the cause of a patient's chronic pain; however, clinicians should not assume a patient is disingenuous if the cause is not discovered.
- The patient's personal and family substance use histories and current substance use patterns should be assessed.
- It is crucial to obtain collateral information on the patient's pain level and functioning, as well as SUD status.
- Comorbid psychological disorders should be assessed and treated.
- Assessment of the patient with co-occurring chronic pain and SUD or other behavioral health disorders should be ongoing.

3 Chronic Pain Management

IN THIS CHAPTER

Overview of Pain Management

Chronic noncancer pain (CNCP) is a major challenge for clinicians as well as for the patients who suffer from it. The complete elimination of pain is rarely obtainable for any substantial period. Therefore, patients and clinicians should discuss treatment goals that include reducing pain, maximizing function, and improving quality of life. The best outcomes can be achieved when chronic pain management addresses co-occurring mental disorders (e.g., depression, anxiety) and when it incorporates suitable nonpharmacologic and complementary therapies for symptom management. Exhibit 3-1 presents the consensus panel's recommended strategy for treating CNCP in adults who have or are in recovery from a substance use disorder (SUD).

The Treatment Team

Chronic pain management is often complex and time consuming. It can be particularly challenging and stressful for clinicians working without input from other clinicians. The effectiveness of multiple interventions is augmented when all medical and behavioral healthcare professionals involved collaborate as a team (Sanders, Harden, & Vicente, 2005). A multidisciplinary team approach provides a breadth of perspectives and skills that can enhance outcomes and reduce stress on individual providers. Although it is ideal when all relevant providers work within the same system and under the same roof, often a collaborative team must be coordinated across a community. This combined effort requires identification of a designated lead care coordinator and a good system of communication among team members and the patient. A treatment team can include the following professionals:

Exhibit 3-4 Steps To Take If Opioid Therapy Is Indicated

Step 1. Educate patient and family about treatment options, sharing the decision about the goal and expected outcome of therapy.

Step 2. Discuss treatment agreement with the patient and family.

Step 3. Obtain a written opioid agreement.

Step 4. Determine and document the treatment plan.

Step 5. Initiate a trial of opioid therapy.

Step 6. Document details of therapy and results.

Department of Veterans Affairs & Department of Defense, 2010.

Key Points

- Pain treatment goals should include improved functioning and pain reduction.
- Treatment for pain and comorbidities should be integrated.
- Non-opioid pharmacological and nonpharmacological therapies, including CAM, should be considered routine before opioid treatment is initiated.
- Opioids may be necessary and should not be ruled out based on an individual's having an SUD history.
- The decision to treat pain with opioids should be based on a careful consideration of benefits and risks.
- Addiction specialists should be part of the treatment team and should be consulted in the development of the pain treatment plan, when possible.
- A substantial percentage of patients with and without SUDs will fail to benefit from prolonged opioid therapy, in which case it should be discontinued, as with any other failed treatment.

4 Managing Addiction Risk in Patients Treated With Opioids

IN THIS CHAPTER

Promoting Adherence

Clinicians should adopt a universal precautions approach toward their patients who have chronic noncancer pain (CNCP) (Exhibit 4-1). The term *universal precautions* first emerged in the context of infectious disease treatment and referred to using infection control procedures with all patients. In the context of pain treatment, a *universal precautions approach* refers to a minimum standard of care applied to all patients who have CNCP, whatever their assessed risk (Gourlay, Heit, & Almahrezi, 2005). A universal precautions approach improves care and shows due diligence in an era of increasing illegal use of prescription opioids.

Clinicians can help patients adhere to treatment plans by:

- Employing treatment agreements.
- Regulating visit intervals.
- Controlling medication supply.
- Conducting urine drug testing (UDT).
- To the degree possible, including the patient's support network in monitoring efforts.

Documenting Care

Meticulous documentation of chronic opioid therapy is essential. It is both a Federal and State requirement, and the quality of documentation can determine whether a clinician is judged to be practicing medicine or trafficking in drugs. In addition, longitudinal documentation is essential to permit a determination over time of the extent to which treatment is an asset or a liability to the patient. Documentation also provides protection for the clinician if drug enforcement authorities conduct an investigation.

The practitioner must be familiar with the requirements of the State in which he or she practices; however, generally there must be documentation of an adequate medical workup of the condition being treated, an evaluation for psychiatric comorbidity including SUD, a plan of care, amounts of scheduled medications prescribed, and instructions for use of medications. Some States require that chronic opioid therapy be used only if other treatments are ineffective or ill-advised. The University of Wisconsin's Pain and Policy Studies Group maintains a Web site that describes the regulations of different States regarding opioid prescribing (http://www.painpolicy.wisc.edu/).

ADRB = Aberrant drug-related behavior

Key Points

- Patients on chronic opioid therapy should be monitored closely for signs of benefit, harm, and ADRBs.
- All ADRBs should be documented, investigated, and acted on.
- Difficult conversations should be managed with compassion and empathy.
- Clinicians should establish and respectfully maintain strict limits with patients who insist on opioids.
- Clinicians should establish relationships with drug-testing laboratory staff and addiction specialists.
- When it is necessary to discontinue chronic opioid therapy, a conscientious tapering plan should be provided.

5 Patient Education and Treatment Agreements

IN THIS CHAPTER

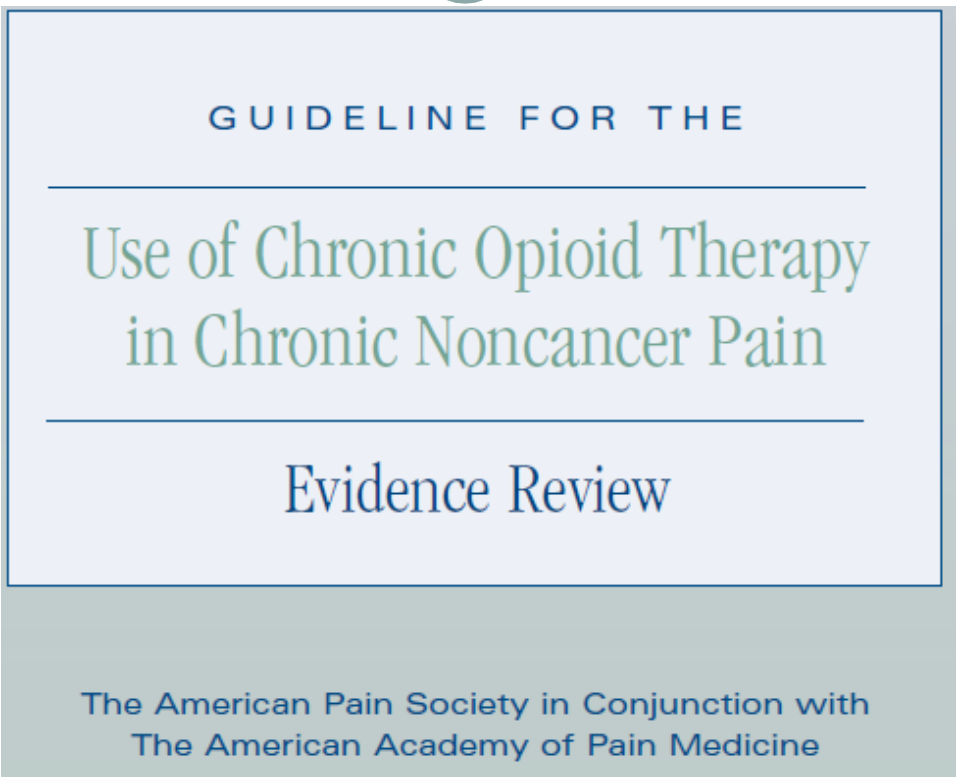
- The Value of Patient Education
- Providing Effective Education
- The Internet as a Source of Patient Education
- Education Content
- Opioid Information
- Methadone Maintenance Therapy Information
- Treatment Agreements
- Key Points

The Value of Patient Education

No randomized controlled trials have specifically evaluated the effect of patient education on treatment outcomes; however, Brox and colleagues (2006) studied 60 patients who had persistent low back pain at least a year after surgery for disc herniation. Patients were randomized to receive either lumbar fusion with transpedicular screws or cognitive intervention, which consisted largely of education on back hygiene and exercises. Outcomes were essentially the same for the two groups.

The potential value of patient education is also supported by ad hoc reviews in the medical literature. For instance, *VA/DoD Clinical Practice Guideline for the Management of Opioid Therapy for Chronic Pain* (Department of Veterans Affairs & Department of Defense [VA/DoD], 2010) recommends both patient and family education, as do other pain treatment guidelines (Chou, Fanciullo, Fine, Adler, et al., 2009; Institute for Clinical Systems Improvement, 2007). Patient education is also necessary for truly informed consent. Geppert (2004, p. 163) defines informed consent as follows: "Informed consent encompasses the capacity to understand the risks, benefits, and alternatives of a treatment, to communicate a choice regarding therapy, to deliberate and reason about the consequences of the proposed medication, and to appreciate how the treatment will affect life and values." Informed consent is particularly important when clinicians are prescribing potentially addictive medications to patients who have histories of substance use disorders (SUDs) and other behavioral health disorders.

STANDARDS?


GUIDELINE FOR THE
Use of Chronic Opioid Therapy in Chronic Noncancer Pain
Evidence Review
The American Pain Society in Conjunction with
The American Academy of Pain Medicine

STANDARDS?

STANDARDS?

PATIENT SELECTION AND RISK STRATIFICATION

(Evaluation/Assessment of Patient and Treatment plan)

- Prior to initiating chronic opioid therapy, practitioner should conduct a history, physical examination and appropriate testing, including an assessment of risk of substance abuse, misuse, or addiction.
- A benefit-to-harm evaluation including a history, physical examination, and appropriate diagnostic testing, should be performed and documented on an ongoing basis during chronic opioid therapy.

Includes obtaining records from prior treaters and review of prescription drug monitoring (PDMP) data

STANDARDS?

INFORMED CONSENT & OPIOID MANAGEMENT PLANS

- When starting chronic opioid therapy, informed consent should be obtained. Continuing discussion with the patient regarding chronic opioid therapy should include goals, expectations, potential risks, and alternatives to chronic opioid therapy.
- Practitioners may consider using a written chronic opioid therapy management plan to document patient and clinician responsibilities and expectations and assist in ongoing patient education.

Includes written pain management agreement with patient

STANDARDS?

MONITORING

(Periodic review)

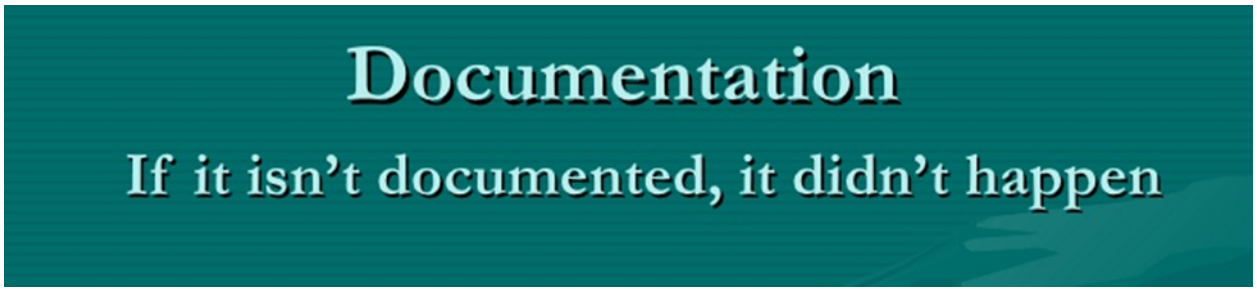
- Practitioners should reassess patients on chronic opioid therapy periodically and as warranted by changing circumstances. Monitoring should include documentation of pain intensity and level of functioning, assessments of progress towards achieving therapeutic goals, presence of adverse events, and adherence to prescribed therapies.
- Practitioners should periodically obtain urine drug screens or other information from patients on chronic opioid therapy to confirm adherence to the chronic opioid therapy plan of care.

Includes consultation and referral or discontinuing opioid treatment

STANDARDS?

MEDICAL RECORDS
(Current, complete and accurate)

- Document
- Document
- DOCUMENT!!!



What Could Be Better


RULES

More Standards!

Washington Administrative Code

WAC § 246-840-467

Patient evaluation. The advanced registered nurse practitioner shall obtain, evaluate, and document the patient's health history and physical examination in the health record prior to treating for chronic noncancer pain.

(1) The patient's health history shall include:

(a) Current and past treatments for pain;

(b) Comorbidities; and

(c) Any substance abuse.

(2) The patient's health history should include:

(a) A review of any available prescription monitoring program or emergency department-based information exchange; and

(b) Any relevant information from a pharmacist provided to advanced registered nurse practitioners.

More Standards!

WAC § 246-840-467 (cont.)

Patient evaluation. * * *

(3) The initial patient evaluation **shall** include:

(a) Physical examination;

(b) The nature and intensity of the pain;

(c) The effect of the pain on physical and psychological function;

(d) Medications including indication(s), date, type, dosage, and quantity prescribed;

(e) A risk screening of the patient for potential comorbidities and risk factors using an appropriate screening tool. The screening should address:

(i) History of addiction;

(ii) Abuse or aberrant behavior regarding opioid use;

(iii) Psychiatric conditions; * * *

(vii) Receipt of opioids from more than one prescribing practitioner or practitioner group;

(viii) Repeated visits to emergency departments seeking opioids; * * *

More Standards!

WAC § 246-840-467 (cont.)

Patient evaluation. * * *

(4) The initial patient evaluation **should** include:

(a) Any available diagnostic, therapeutic, and laboratory results; and

(b) Any available consultations.

(5) The health record shall be maintained in an accessible manner, readily available for review, and should include:

(a) The diagnosis, treatment plan, and objectives;

(b) Documentation of the presence of one or more recognized indications for the use of pain medication;

(c) Documentation of any medication prescribed;

(d) Results of periodic reviews;

(e) Any written agreements for treatment between the patient and the advanced registered nurse practitioner; and

(f) The advanced registered nurse practitioner's instructions to the patient.

More Standards!

WAC § 246-840-470

Treatment plan.

(1) The written treatment plan shall state the objectives that will be used to determine treatment success and shall include, at a minimum:

(a) Any change in pain relief;

(b) Any change in physical and psychosocial function; and

(c) Additional diagnostic evaluations or other planned treatments.

(2) After treatment begins the advanced registered nurse practitioner should adjust drug therapy to the individual health needs of the patient. Advanced registered nurse practitioners shall include indications for medication use on the prescription and require photo identification of the person picking up the prescription in order to fill. Advanced registered nurse practitioners shall advise the patient that it is the patient's responsibility to safeguard all medications and keep them in a secure location.

(3) Other treatment modalities or a rehabilitation program may be necessary depending on the etiology of the pain and the extent to which the pain is associated with physical and psychosocial impairment.

WAC § 246-840-473

Informed consent. The advanced registered nurse practitioner shall discuss the risks and benefits of treatment options with the patient, persons designated by the patient, or with the patient's surrogate or guardian if the patient is without health care decision-making capacity.

More Standards!

WAC § 246-840-475

Written agreement for treatment. Chronic noncancer pain patients should receive all chronic pain management prescriptions from one advanced registered nurse practitioner and one pharmacy whenever possible. If the patient is at high risk for medication abuse, or has a history of substance abuse, or psychiatric comorbidities, the prescribing advanced registered nurse practitioner shall use a written agreement for treatment with the patient outlining patient responsibilities. This written agreement for treatment shall include:

(1) The patient's agreement to provide biological samples for urine/serum medical level screening when requested by the advanced registered nurse practitioner;

(2) The patient's agreement to take medications at the dose and frequency prescribed with a specific protocol for lost prescriptions and early refills;

(3) Reasons for which drug therapy may be discontinued (e.g., violation of agreement);

(4) The requirement that all chronic pain management prescriptions are provided by a single prescriber or multidisciplinary pain clinic and dispensed by a single pharmacy or pharmacy system;

(5) The patient's agreement to not abuse alcohol or use other medically unauthorized substances;

More Standards!

WAC § 246-840-475 (cont.)

Written agreement for treatment. * * * This written agreement for treatment shall include: * * *

(6) A written authorization for:

(a) The advanced registered nurse practitioner to release the agreement for treatment to local emergency departments, urgent care facilities, and pharmacies; and

(b) Other practitioners to report violations of the agreement back to the advanced registered nurse practitioner;

(7) A written authorization that the advanced registered nurse practitioner may notify the proper authorities if he or she has reason to believe the patient has engaged in illegal activity;

(8) Acknowledgment that a violation of the agreement may result in a tapering or discontinuation of the prescription;

(9) Acknowledgment that it is the patient's responsibility to safeguard all medications and keep them in a secure location; and

(10) Acknowledgment that if the patient violates the terms of the agreement, the violation and the advanced registered nurse practitioner's response to the violation will be documented, as well as the rationale for changes in the treatment plan.

More Standards!

WAC § 246-840-477

Periodic review. The advanced registered nurse practitioner shall periodically review the course of treatment for chronic noncancer pain, the patient's state of health, and any new information about the etiology of the pain. Generally, periodic reviews shall take place at least every six months. However, for treatment of stable patients with chronic noncancer pain involving nonescalating daily dosages of forty milligrams of a morphine equivalent dose (MED) or less, periodic reviews shall take place at least annually.

(1) During the periodic review, the advanced registered nurse practitioner shall determine:

(a) Patient's compliance with any medication treatment plan;

(b) If pain, function, or quality of life have improved or diminished using objective evidence, considering any available information from family members or other caregivers; and

(c) If continuation or modification of medications for pain management treatment is necessary based on the advanced registered nurse practitioner's evaluation of progress towards treatment objectives.

(2) The advanced registered nurse practitioner shall assess the appropriateness of continued use of the current treatment plan if the patient's progress or compliance with current treatment plan is unsatisfactory.
* * *

(3) The advanced registered nurse practitioner should periodically review information from any available prescription monitoring program or emergency department-based information exchange.

(4) The advanced registered nurse practitioner should periodically review any relevant information from a pharmacist provided to the advanced registered nurse practitioner.

At least …

AT LEAST … A POLICY

STATE OF MICHIGAN
DEPARTMENT OF COMMUNITY HEALTH
LANSING

JENNIFER M. GRANHOLM
GOVERNOR

JANET OLSZEWSKI
DIRECTOR

Michigan Board of Nursing Guidelines for the Use of Controlled Substances for the Treatment of Pain

Section I: Preamble

The Michigan Board of Nursing recognizes that principles of quality nursing practice dictate that the people of the State of Michigan have access to appropriate and effective pain relief. The appropriate application of up-to-date knowledge and treatment modalities can serve to improve the quality of life for those patients who suffer from pain as well as reduce the morbidity and costs associated with untreated or inappropriately treated pain. The Board encourages nurses to view effective pain management as a part of quality nursing practice for all patients with pain, acute or chronic, and it is especially important for patients who experience pain as a result of terminal illness. All nurses should become knowledgeable about effective methods of pain treatment as well as statutory requirements for prescribing controlled substances.

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Section II: Advanced Practice Nurse Guidelines

Advanced practice nurses who are authorized by law to prescribe or dispense drugs, including controlled substances, should recognize that tolerance and physical dependence are normal consequences of sustained use of opioid analgesics and are not synonymous with addiction. Prescribing or dispensing controlled substances, including opioid analgesics, to treat pain is considered a legitimate medical purpose if based upon sound clinical grounds.

There are many effective treatments for pain; opioid analgesics play an important role, especially when pain is moderate to severe. For many patients, opioid analgesics—when used as recommended by established pain management guidelines are the most effective way to treat their pain, and are often the only treatment option that provides significant relief.

The following principles are not intended to define complete or best practice, but rather to communicate what the Michigan Board of Nursing considers to be within the boundaries of professional practice.

AT LEAST … A POLICY

Principles

1. Assessment of the Patient

A complete health history and physical examination must be conducted and documented in the health record.

2. Treatment Plan

The written treatment plan should state objectives that will be used to determine treatment success, such as pain relief and improved physical and psychosocial function, and indicate if any further diagnostic evaluation or other treatments are planned. After treatment begins, the drug therapy plan should be adjusted to the individual medical needs of each patient. Other treatment modalities or a rehabilitation program may be necessary depending on the etiology of the pain and the extent to which the pain is associated with physical and psychosocial impairment.

3. Informed Consent

The advanced practice nurse should discuss the risks and benefits of the use of controlled substances with the patient, persons designated by the patient, or with the patients surrogate or guardian if the patient is incompetent or a minor.

AT LEAST … A POLICY

4. Agreement for Treatment of High-Risk Patients

If the patient is determined to be at high risk for medication abuse or to have a history of substance abuse, or at the discretion of the prescriber, the advanced practice nurse will obtain a written agreement from the patient outlining patient responsibilities, including:

- Submitting to screening of urine/serum medication levels when requested;
- Limiting prescription refills only to a specified number and frequency;
- Requesting or receiving prescription orders from only one health care provider;
- Using only one pharmacy for filling prescriptions; and
- Acknowledging reasons for which drug therapy maybe discontinued (i.e. violation of agreement).

5. Periodic Review

At reasonable intervals based on the individual circumstances of the patient, the course of treatment and any new information about the etiology of the pain should be evaluated. The advance practice nurse involved with the management of pain should evaluate progress toward meeting treatment goals in light of improvement in the patients' pain intensity and improved physical or psychosocial function i.e., ability to work, use of health care resources, activities of daily living, quality of life. If treatment goals are not being achieved despite medication adjustments, the health care provider's should reevaluate and alter the treatment plan.

AT LEAST … A POLICY

6. Consultation

The advanced practice nurse should be willing to refer the patient for additional evaluation and treatment as necessary in order to achieve treatment goals.

7. Medical Records

The advanced practice nurse should keep accurate and complete records to include:

- The medical history and physical examination including:
  a. The nature and intensity of the pain, including treatment for any underlying or coexisting conditions; and,
  b. Presence of one or more recognized medical indications for the use of a controlled substance.
- Diagnostic, therapeutic, and laboratory results.
- Evaluations and consultations.
- Treatment goals.
- Discussion of risks and benefits, including treatment contract, if one has been established.
- Treatments.
- Medications including date, type, dosage, and quantity prescribed.
- Instructions and agreements.
- Periodic reviews.

AT LEAST … A POLICY

AT LEAST … A POLICY

Before Prescribing or Dispensing

Develop and maintain competence

Prescribers, including prescribers who dispense, must maintain competence to assess and treat pain to improve function. This includes understanding current, evidenced-based practices and using other resources and tools related to opioid prescribing and dispensing. In some clinical situations consultation with a specialist is appropriate. Pharmacists must maintain competence in the appropriateness of therapy. See the Appendix for a list of resources and tools for developing and maintaining competence.

Utilize safeguards for the initiation of pain management

The decision to prescribe or dispense opioid medication for outpatient use may be made only after a proper diagnosis and complete evaluation which should include a risk assessment, pain assessment, and review of relevant PDMP data. These safeguards apply to acute and chronic, non-cancer pain but not to palliative end-of-life care.

Not all pain requires opioid treatment. Prescribers should not prescribe opioids when non-opioid medication is both effective and appropriate for the level of pain.

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1. Diagnose

Prescribers should establish a diagnosis and legitimate medical purpose appropriate for opioid therapy through a history, physical exam, and/or laboratory, imaging or other studies. A bona fide provider-patient relationship must exist.

2. Assess Risk

Prescribers should conduct a risk assessment prior to prescribing opioids for outpatient use and again before increasing dosage or duration. Risk assessment is defined as identification of factors that may lead to adverse outcomes and may include:

- Patient and family history of substance use (drugs including alcohol and marijuana)
- Patient medication history (among other reasons, this is taken to avoid unsafe combinations of opioids with sedative-hypnotics, benzodiazepines, barbiturates, muscle relaxants or to determine other drug-drug interactions)
- Mental health/psychological conditions and history
- Abuse history including physical, emotional or sexual
- Health conditions that could aggravate adverse reactions (including COPD, CHF, sleep apnea, elderly, or history of renal or hepatic dysfunction)
- Prescribers and dispensers should observe the patient for any aberrant drug-related behavior and follow-up appropriately when aberrant drug-related behavior is presented. See the Appendix for a description of such behaviors.

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3. Assess Pain

An appropriate pain assessment should include an evaluation of the patient's pain for the:

- Nature and intensity
- Type
- Pattern/frequency
- Duration
- Past and current treatments
- Underlying or co-morbid disorders or conditions
- Impact on physical and psychological functioning

4. Review PDMP

Prescribers and dispensers should utilize the Prescription Drug Monitoring Program (PDMP) prior to prescribing or dispensing opioids.

Collaborate with the healthcare team

Prescribers and dispensers should collaborate within the healthcare team to prevent under-prescribing, over-prescribing, misuse and abuse of opioids. See the Appendix for additional resources.

AT LEAST … A POLICY

Patient Education

Prescribers should educate patients regardless of the dosage, formulation and duration of opioid therapy on proper use, risks of addiction, alternatives, storage, and disposal of opioids and the potential for diversion (see the Appendix for resources on disposal). Risks may include but are not limited to: overdose, misuse, diversion, addiction, physical dependence and tolerance, interactions with other medications or substances, and death.

Discontinuing Opioid Therapy

The prescriber should consider discontinuing opioid therapy when:

- The underlying painful condition is resolved;
- Intolerable side effects emerge;
- The analgesic effect is inadequate;
- The patient's quality of life fails to improve;
- Functioning deteriorates; or
- There is aberrant medication use.

caveat

COURTS DO NOT ALWAYS GIVE THE SAME WEIGHT TO POLICIES AS RULES

e.g.

Within this statutory framework, the Board enacted its Pain Rules. As noted previously in this opinion, the Board recognized that promulgation of pain management guidelines and rules benefits physicians by giving clear guidance in this difficult area of medical practice and their patients. It appears that these rules also benefit patients suffering chronic pain who must, in conjunction with the advice of their physicians, balance the helpfulness of controlled substances in pain management against the risk of dependency and addiction. As the Board argues, the guidelines and rules do not limit or control the physician's ultimate authority to treat his patient, but define a mechanism by which all concerned can be given some assurance that the physician is following sound medical practice in his prescribing decisions.

Jarrott v. Louisiana State Bd. of Med. Examiners, 2004-1714 (La. App. 4 Cir. 8/25/09), 19 So. 3d 526, 555.

thank you